

APPLICANT(S): LEVY, Andrew  
SERIAL NO.: 10/748,177  
FILED: December 31, 2003  
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### REMARKS

Claims 1, 12-15, and 26-28 were pending in the application. Claims 1 and 15 have been amended.

The present response is intended to be fully responsive to all points rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

#### **Claim Rejections: 35 U.S.C. § 112 - Enablement**

The Examiner rejected claims 1, 12-15 and 26-28 under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. The Examiner contends that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner provided a detailed discussion of the factors set forth in *in re Wands*. Among the factors and Examiner's points pertaining thereto is a need for replication of earlier studies to establish the relationship between vitamin E administration and cardiovascular benefit. The Examiner identified the inventor's published comments that a 1500 patient study is underway to validate earlier findings.

Applicants request reconsideration of the rejection in light of the publication of the above-mentioned study, and the foregoing amendments to the claims.

In accordance with Milman et al., 2008, "Vitamin E supplementation reduces cardiovascular events in a subgroup of middle-aged individuals with both type 2 diabetes mellitus and the haptoglobin 2-2 genotype: a prospective double-blinded clinical trial," published in *Arteriosclerosis, Thrombosis and Vascular Biology*, vol. 28, pp. 341-7 (Epub 2007 Nov 21; copy attached and IDS Form PTO-892), in a study on 1434 diabetic, Hp 2-2 randomized to vitamin E or placebo, a statistical correlation was observed between vitamin E treatment and risk of myocardial infarction (Table 2). In this study, diabetic individuals 55 years or older were enrolled; thus Applicants have incorporated the age limitation from page 36, line 5, into claims 1 and 15. Thus, Applicants, by virtue of the amendments to the claims presented above, have focused the claimed correlation on myocardial infarction, and hereby

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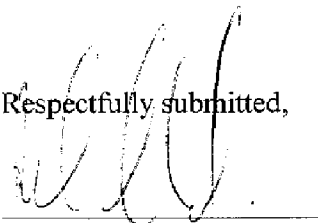
request reconsideration of the rejection. In view of the foregoing amendments and remarks, the pending claims are believed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Furthermore, rejoinder of the withdrawn claims of Group I, claims 6-11 and 20-25, is requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned.

Please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,



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Dated: November 3, 2008

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Milman et al., 2008.